

### Remarks

The Office Action mailed October 18, 2002 has been received and reviewed. Claims 1-8, 10-13, 15 and 18-26 are pending in the present application. All stand finally rejected. Applicants propose amending the application as previously set forth. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

1. **35 USC 102(a) & van Oosterhout et al.**

All pending claims were rejected as being anticipated by van Oosterhout et al. The earlier declarations of Dr. van Oosterhout and Dr. van Emst submitted to overcome the rejection ("applicants' own work") were rejected for failure to comply with M.P.E.P. § 715.05. Applicants submit herewith replacement Declarations complying with the requirement. Accordingly, applicants request that the rejection be withdrawn.

2. **The Prior Art Based Rejections**

Claims 1-5, 7, 9-13, 15, 18, 19 and 21-26 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by WO 89/06967 to Scannon et al. (hereinafter "Scannon"). Claims 1-8, 10-13, 15, and 18-23 also have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Scannon in view U.S. Patent 6,261,535 to Thorpe et al. Applicants propose amending the claims, as per the Examiner's helpful suggestion, and, accordingly, request that these rejections be withdrawn.

It was stated in the Office Action that it is current Office policy to treat "consisting essentially of" transitional language as equivalent in scope to "comprising" transitional language. *But see*, M.P.E.P. § 2111.03, p. 2100-50 (Aug. 2001). The Examiner then suggested that the "issue could be unambiguously addressed by a claim that recited that the composition did not contain antibodies other than those that bind CD3 and CD7." (Office Action, pages 2 & 3).

Applicants hereby adopt the Examiner's suggestion, and propose amending independent claims 1 and 15, to unambiguously state "wherein said pharmaceutical composition contains no antibodies other than those antibodies that bind CD3 and those antibodies that bind CD7".

Similarly, independent claims 24 and 25 are to be amended to utilize "consisting of" transitional language (not "consisting essentially of") which should also unambiguously address the issue in a different manner. M.P.E.P. § 2111.03, p. 2100-50 (Aug. 2001).

Basis for these amendments is inherent throughout the application, but specific basis can be found at page 11 and the abstract of the application as filed. It is thus respectfully submitted that no new matter has been added.

As discussed at the interview, Scannon is merely an invitation to experiment. It does not disclose a specific formulation having first molecules directed against CD3, and second molecules, distinct from the first molecules, directed against CD7, wherein at least one of the first and said second molecules includes a toxic moiety. It is only a laundry list of options. It has a generic disclosure, but no specific disclosure of the instantly claimed invention. At worst, the reference would be "an obvious to try" reference with respect to the instantly claimed invention, which is not the applicable standard. *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988). A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts might be carried out, and the teachings of Scannon, even in combination with the other prior art of record, fail to suggest the claimed invention. *Id.* Further, nothing in the reference would lead one to the unexpected results obtained by the invention.

Thorpe et al. is even further away from the instant invention. Accordingly, entry of the amendments and withdrawal of the rejections is requested.

### 3. **Amendments to the Specification**

The substitute specification submitted with the response of June 11, 2002 was not entered for failure to include a statement pursuant to Rule 125(b)(1). Pursuant to 37 C.F.R. 1.125(b)(1), applicants state, through their undersigned counsel, that the substitute specification submitted June 11, 2002 contains no new matter. Applicants have not resubmitted the substitute specification to keep the size of the file manageable. If the Office would like, however, applicants will promptly resubmit the substitute specification upon telephone request.

4. **Entry of Amendments**

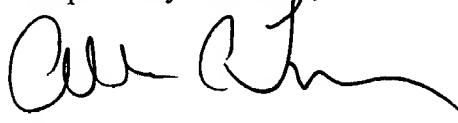
Applicants respectfully request entry of the proposed amendments. As previously explained, no new matter has been added. The amendments should place the application in condition for allowance. In the event they do not, they certainly remove issues for appeal and should be entered for that reason. They also only adopt examiner suggestions.

No new issues are presented and no new search should be required as the same arguments were presented in the last response (based instead on the "consisting essentially of" transitional language instead). The amendments were not earlier made because although current Office practice may be to interpret "consisting essentially of" as "comprising", this is not the standard enunciated by the Federal Circuit or the one recited in the M.P.E.P., and applicants could not be expected to anticipate that such a standard is current Office policy. *See, M.P.E.P. § 2111.03, p. 2100-50 (Aug. 2001).*

**Conclusion**

In view of the amendment and remarks, the claims are believed to be in condition for allowance. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is kindly invited to contact applicants' attorney at the telephone number given herein.

Respectfully submitted,



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Enclosures: Declarations

## VERSION OF CLAIMS WITH MARKINGS TO SHOW CHANGES MADE

1. (Three times amended) A pharmaceutical composition for eliminating or reducing the number of unwanted CD3 and/or CD7 positive cells, said pharmaceutical composition consisting essentially of:

first molecules directed against CD3, and

second molecules, distinct from said first molecules, said second molecules directed against CD7, wherein at least one of said first and said second molecules include a toxic moiety and

wherein said pharmaceutical composition contains no antibodies other than those antibodies that bind CD3 and those antibodies that bind CD7.

15. (Three times Amended) A method of treating a disease state in a subject believed to be suffering therefrom, said disease state comprising at least one of Graft vs. Host disease, graft rejections, T-cell leukemias, T-cell lymphomas, other lymphomas, other CD3 and/or CD7 malignancies, autoimmune diseases, and infectious immune disease, said method comprising administering to the subject an amount of a pharmaceutical composition consisting essentially of:

first molecules directed against a CD3 positive cell, and

second molecules, distinct from said first molecules, directed against a CD7 positive cell, wherein at least the second molecules include a toxic moiety and

wherein said pharmaceutical composition contains no antibodies other than those antibodies that bind CD3 and those antibodies that bind CD7.

24. (Amended) A pharmaceutical composition for eliminating or reducing the number of unwanted CD3 and/or CD7 positive cells, said pharmaceutical composition consisting [essentially] of:

anti-CD3 antibodies; and

anti-CD7 antibodies, wherein each of said anti-CD3 antibodies and said anti-CD7 antibodies include a toxic moiety.

25. (Amended) A method of treating a disease state in a subject believed to be suffering therefrom, said disease state comprising at least one of Graft vs. Host disease, graft rejections, T-cell leukemias, T-cell lymphomas, other lymphomas, other CD3 and/or CD7 malignancies, autoimmune diseases, and infectious immune diseases, said method comprising administering to the subject an amount of a pharmaceutical composition consisting [essentially] of:

anti-CD3 antibodies; and

anti-CD7 antibodies, wherein each of said anti-CD3 antibodies and said anti-CD7 antibodies include a toxic moiety.